K120503

JUN 18 2012

510(K) SUMMARY

Submitter:

Hee Seok Jung
neobiotech Co., Ltd.
e-space #103, 104-1, 104-2, 105, 106, 205, 212, 312, 509,511,10th floor, Guro-dong, Guro-gu, Seoul, Korea 152-789
Phone: 82-53-857-5770
Fax: 82-53-857-5432

Contact /US agent:

April Lee
Kodent, Inc.
325 N. Puente St. Unit B
Brea, CA 92821

Phone: 714-525-0114
Fax: 714-525-0116

Device Information:

Device Name: CMI Implant IS II active

Classification Name: Implant, Endosseous, Root-Form

Common Name: Endosseous Dental Implant

Classification: Class II

Product Code: DZE

Regulation number: 21 CFR 872.3640

Date prepared: 5/21/2012

Device Description

Neo CMI Implant IS II active system is dental implant consist of pure titanium, grade 4. The titanium implant surface was sandblasted with large grits and acid etched (S.L.A.) This implant system can be used for all oral endosteal implant indications in the mandible and maxilla, for functional and esthetic oral rehabilitation of edentulous. The fixture diameters are 3.8, 4.3, 4.5, 5.0, 5.5, 6.0, 7.0, 8.0 and the lengths are 7.3, 8.5, 10.0, 11.5, 13.0, and 15.0.

Indications for use

The CMI Implant IS II active is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetics devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

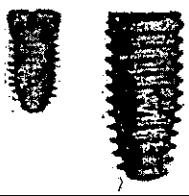
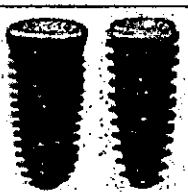
K120503

Non Clinical Study Data

Static Compressive Load Test Data was provided to identify substantial equivalence of modifications from the predicate device.

Predicate devices

CMI Implant IS System (K113554) manufactured by neobiotech Co., Ltd.

		Subject Device	Predicate Device
Product Name		CMI Implant IS II active	CMI Implant IS System
510(k)		N/A	K113554
Manufacturer		neobiotech Co., Ltd.	neobiotech Co., Ltd.
Shape			
Intended use		Identical to the predicate	for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
Composition of Material		Titanium Grade 4 of ASTM F 67	Titanium Grade 4 of ASTM F 67
Device design	**Dia(Ø)**	Identical to the predicate	3.5/4.0/4.5/5.0/5.5/6.0/7.0/8.0
	Length(mm)	Identical to the predicate	7.0/7.3/8.5/10.0/11.5/13.0/15.0
Surface treatment		S.L.A	RBM
Biocompatibility		Yes	Yes
Sterilization		Gamma Sterilization	Gamma Sterilization

K120503

Summary of Substantial Equivalence Comparison

The CMI Implant IS II active is the same device characteristics as the predicate device,CMI Implant IS System; intended use, material, design and use concept are similar.
Based on the comparison of intended use and technical features, CMI Implant IS II active is substantially equivalent to the predicate device.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification neobiotech Co., Ltd. concludes that the CMI Implant IS II active is substantially equivalent to predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2012

Kodent, Incorporated
C/O Ms. April Lee
Consultant
Neobiotech Company Limited
325 North Puente Street, Unit B
Brea, California 92821

Re: K120503
Trade/Device Name: CMI Implant IS II Active
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 21, 2012
Received: May 24, 2012

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K100503

Device Name: CMI Implant IS II active

Indications for Use:

The CMI Implant IS II active is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetics devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use _____X_____ **AND/OR** **OverThe-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100503